PROTOCOL OF THESIS FOR PARTIAL FULFILMENT OF MD DEGREE IN OBSTETRICS & GYNAECOLOGY

Title of the Protocol: Impact of using synthetic absorbable monofilament versus multifilament suture material for uterine closure on the development of uterine Isthmocele: A randomized controlled clinical trial

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What is already known on this subject? AND What does this study add?

Cesarean section is one of the most common operative procedures performed in modern obstetrics **(Mackeen et al., 2012)**, that become increasingly common in both developed and developing countries for a variety of reasons today **(Vogel et al., 2015)**, thus any useful refinement in the operative technique, however minimal, is likely to yield substantial benefits. Closure of the uterine incision is a key step in caesarean section, and it is imperative that an optimal surgical technique be employed for closing a uterine scar. This technique should be able to withstand the stress of subsequent labor. . **(Yazicioglu, 2006).**

Cesarean section can effectively prevent maternal and perinatal mortality and morbidity. However, there are many short and long-term complications of Cesarean section. One of the most common complications is the isthmocele, which was first described by Morris in 1995, as a wedge-shaped distortion at the uterine incision site. **(Gubbini G et al.,2008)**.

Isthmocele, also known as a niche, an isthmocele, or Cesarean scar dehiscence, has been implicated as a factor in clinical problems as uterine rupture, and cesarean scar ectopic pregnancy. **(Morris H et al.,1995).**

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In this study we aim at comparing using synthetic absorbable monofilament sutures in uterine closure during caesarean delivery with using synthetic absorbable multifilament sutures as regards the reduction in the rate of isthmocele.

1.INTRODUCTION/ REVIEW

Cesarean section is the most common type of obstetric surgery **(Mistry k et al.,2013)** with substantial increases in the number of Cesarean section deliveries in middle- and high-income countries in recent years.(**Betrán AP et al.,2014**). The rates of caesarean section vary by region, accounting for 3.3% of deliveries in Africa, 33.7% in Latin America, 27.3% In Asia, and 40.5% in China, with a global average of 15.9% **(WHO,2009).** However, there are short and long-term complications of Cesarean section, including effects on other surgical procedures, as well as on subsequent Cesarean section operations. One of the most common complications is the isthmocele, which is noted more frequently with increasing Cesarean section operations. **(Villar J et al.,2007).**

Isthmocele can develop after transverse incision of the lower uterine segment. This pouch-like structure, first described by Morris in 1995, also called isthmocele, niche, or caesarean scar dehiscence, is located at the site of the old caesarean scar on the anterior uterine isthmus. **(Baranov A et al.,2016).**

Sutures are an essential part of any major surgery, serving to hold opposing tissues together and accelerate the healing process, resulting in decreased scarring of the affected areas.

Many authors have investigated possible risk factors related to isthmocele, particularly those

related to uterine closure, number of caesarean births, uterine position, and labour before caesarean delivery. **(Tower AM1 et al., 2013).** However, studies examining the role of the suture material in formation of isthmocele are limited.

Isthmocele has been implicated as an etiologic factor in clinical problems, such as rupture of the uterus during a subsequent pregnancy, ectopic pregnancy at the caesarean scar, caesarean scar endometriosis, secondary infertility, postmenstrual spotting and dysmenorrhea. . (**Bij de Vaate AJ, 2011).**

The development of isthmocele is associated with a deficiency of uterine scar healing. The prevention of isthmocele should be the first and most essential aim of overcoming isthmocele-related complications. Therefore, numerous studies have recently focused on the development and prevention of isthmocele. (**McCurdy R et al.,2017).**

To assess the healing of scar and the risk of uterine rupture and other complications, ultrasonography is used in the evaluation of uterine scar 6 weeks after delivery. It has generally been found that, the thicker the uterine scar, the lower the rate of complications. This may be due to that the thicker scar is stronger, and thus performs better than a thinner one. ***(Litzka, 2021).***

Closure of the uterine incision is a key step in caesarean delivery, correct approximation of the cut margins is of a critical value. ***(Vikhareva Osser , 2011).*** Limited data are available to evaluate the role of the suture materials in uterine scar healing and the development of isthmocele. (**Başbuğ A et al.,2019).**

Monofilament suture (polyglycolide-co-caprolactone) material is made of a single strand, which is relatively more resistant to harboring microorganisms. It also exhibits less resistance to passage through tissue unlike multifilament suture which inflict more microtrauma as they pass through tissues. However, great care must be taken in handling and tying a monofilament suture, because crushing or crimping of the suture can weaken it and lead to undesirable and premature suture failure. Multifilament suture material (polyglactin) is composed of several filaments twisted or braided together. It generally has greater tensile strength and better pliability and flexibility than monofilament suture material, and it handles and ties well. Multifilament sutures also induce a more intense inflammatory response and contribute to larger knot volumes than monofilaments. However, because multifilament materials have increased capillarity, the increased absorption of fluid may facilitate the introduction of pathogens, which increases the risk for wound infection and dehiscence. **(Islam A, et al.2011)**

An internationally recognized definition for isthmocele was only agreed upon in 2019 by the European task force, which defined a cesarean scar defect as an “indentation at the site in the cesarean section scar with a depth of at least 2 mm.” This definition was further subclassified as follows: simple niche, simple niche with one branch, and complex niche (with more than one branch). A branch was defined as the thinner part of the main niche that is directed toward the serosa and has a width smaller than the main niche. Residual myometrial thickness "RMT" is the distance between the tip of the hypo echoic triangle and the surface of anterior uterine wall measured by mm.) At the apex of the main niche, the RMT is often decreased. **(Jordans IPM et al,2019).**

The present study aimed to evaluate how the use of Monocryl (monofilament synthetic

absorbable sutures) instead of Vicryl (multifilament synthetic absorbable sutures) in the continuous double-layer unlocked closure technique for low transverse uterine incisions impacts uterine scar healing after Cesarean section.

2.AIM / OBJECTIVES

To evaluate the impact of using synthetic absorbable monofilament sutures in uterine closure during caesarean delivery compared to using synthetic absorbable multifilament sutures on the development of Isthmocele.

Research Question:

Will uterine closure using synthetic absorbable monofilament sutures during caesarean delivery reduce the incidence of isthmocele compared to uterine closure using synthetic absorbable multifilament sutures?

3.METHODOLOGY:
Patients and Methods/ Subjects and Methods/ Material and Methods

- **Study Type:** A Randomized Controlled Trial.
- **Study Setting:** The study will be conducted at Ain Shams University Maternity Hospital (labour ward and the Ultrasound (Special Care unit for the fetus).
- **Study Period:** 1 year. (from December 2023 to December 2024)
- **Sampling Method:** Convenience sample from El-Demrdash hospital population that attending the ER.
- **Study Population:** The study will be conducted on (140) women divided into two equal groups.
- **Sample Justification:** Based on the results of **Saccone *et al.* (2022),** with the mean defect width in mm in monofilament group 2.9 ± 0.6 and in multifilament group 3.4 ±1 mm, alpha error 5% and power of study 80%, the required sample is 140 patients 70 in each group. The program for sample size calculation is STATA 10.

Inclusion criteria:

- Age: 20-45 years old
- Singleton pregnancy.
- Gestational age between 37 completed weeks to 42 weeks.
- Patients undergoing elective primary caesarean section

Exclusion criteria:

- History of uterine surgery (e.g. hysterotomy, myomectomy, perforation, caesarean section). (to be able to differentiate between the recent CS scar and the old scar)
- Abnormal placental invasion (placenta previa and accrete) (more liable to undergo Cesarean hysterectomy)
- Uterine anomalies (e.g., septum, Mullerian anomalies or fibroids). (may be localized at the suture line and therefore affect the scar)

- Drugs intake that affects bleeding or tissue healing e.g., anti-coagulants, immunosuppressive drugs and chronic use of steroids (more than 14 days pre-operative)
- Any medical Co-morbidity (diabetes mellitus, Hypertension and Thyroid abnormalities) (more liable to affect the healing)

- **Randomization**:

Randomization will be done using computer generated random sequence. Study population will be randomized into one of the two groups:

- Group (I): 70 patients will undergo uterine closure using Monofilament suture material. (A) (1/0, Monocryl®).
- Group (II): 70 patients will undergo uterine closure using Multifilament suture material. (B) (1/0, Vicryl®).

- **Allocation concealment**:

One hundred and forty opaque envelopes will be numbered serially and each envelope with the corresponding number which denotes the allocated group will be put according to randomization table. Then all envelopes will be closed and put in one box. When the first patient is included, the first envelope will be opened and the patient will be allocated according to the letter inside.

- **Blinding:**

Double blinding is difficult because the surgeon will perform the procedure. However, the measured outcomes are objective and unlikely to be biased by lack of blinding. Patient is blinded, sonography (measuring the outcome is blind to type of repair). Statistical analysis will be blinded to group allocation (single blinded)

- **Study procedures and interventions:**

The patients will be randomly divided into 2 groups using a computer-generated number based on the type of suture materials to be used for the continuous double-layer unlocked closure of the low transverse uterine incision during Cesarean section.

Surgery will be done by the most senior resident.

Baseline Evaluation

All participants will be submitted to:

- Complete history taking including personal history, history of present pregnancy, past history, menstrual history, obstetric history, medical history and family history.
- General, abdominal, and pelvic examination.
- Laboratory investigation: complete blood picture, coagulation profile, random blood sugar, liver enzymes and serum creatinine.
- Ultrasound examination: Basic ultrasound examination will be done for all women to assess (fetal life, Biometry, amniotic fluid and placental location).

Preoperative antibiotic prophylaxis:

Two grams of cefazolin (under trade name of ***Zinol***® manufactured by Pharco B International, New Borg El Arab, Egypt.) to be administered 15 – 60 minutes before incision. ***(Bratzler et al., 2013, Witt et al, 2013).***

Anesthesia: All anesthesia techniques can be considered.

Operative steps: "All surgeries will be performed by the same surgeon rank".

- Antisepsis of urethral meatus and catheterization under aseptic conditions.
- Vaginal toilet will be done to all patients with povidone iodine solution before the operation.
- Scrubbing the abdomen will be done by using povidone iodine solution 10%.
- All women will undergo Pfannenstiel-Kerr cesarean section.
- Open of the anterior abdominal wall in layers by scalpel.
- Lower segment uterine incision.
- Deliver of the head by firm wrist flexion, then insertion of fingertips into the uterine incision and advance them around the fetal head to deliver the shoulder and the body
- Deliver the placenta by controlled cord traction.
- Oxytocin (5 IU by slow intravenous injection) will be used to encourage contraction of the uterus and to decrease blood loss.
- After delivery of the fetus and placenta:

Group (A):"Interventional group"

Closure of the uterus in two layers in continuous unlocked sutures using synthetic absorbable monofilament suture (Monocryl 1). (EGYMONOCRYL® manufactured by Taisier-Med Obour, Egypt).

Group (B):"Control Group"

Closure of the uterus in two layers in continuous unlocked sutures using synthetic absorbable multifilament suture (Vicryl 1) (EGYSORB® manufactured by Taisier-Med Obour, Egypt).

- Fascia will be closed as continuous running sutures using an absorbable suture (Vicryl 1*)*
- Subcutaneous closure: The subcutaneous adipose layer should be closed when the layer is ≥ 2 cm by Vicryl 0. ***(Chelmow et al., 2004)***.
- Skin closure: Reapproximation of the skin will be performed with subcuticular suture using 2-0 polypropylene nonabsorbable suture (EGYPROLENE® manufactured by Taisier-Med Obour city, Cairo, Egypt.).

Post-operative care:

- ➢ All patients will receive Non-Steroidal Anti-Inflammatory drugs immediately postoperative then one ampoule 12 hours postoperative, ***(Altman, 2015).*** and according to Ain Shams Maternity hospital protocol.
- Vital signs (pulse, blood pressure, temperature) of the patients will be measured four times daily during hospitalization.
- At 6 h postoperatively, urinary Foley catheters will be removed and oral intake with clear fluids will be started. ***(ACOG, 2008).***
- A venous blood sample for complete blood count examination will be withdrawn after 24 hours postoperative.
- Regular antipyretic will not be used so as not to mask possible postpartum pyrexia.

- Patients will be instructed for postoperative wound care e.g.: to always keep wound dressing dry and clean and in case it gets wet it is to be dressed in an aseptic non-touch technique.
- Follow up for assessment after 1 week of delivery to check the wound, and after 6 months to undergo the Ultrasound.

Outcomes:

Primary outcome: the incidence of isthmocele by transvaginal ultrasound 6 months after delivery.

isthmocele is defined as an anechoic defect communicating with the endometrial cavity at the anterior wall of the lower uterine segment.

For each case the following isthmocele measurements will be obtained:

1. The thinning extent, calculated by a ratio between (a) and (b).
   (a): thickness of the residual myometrium over the defect.
   (b): total intact myometrium. A severe deficiency occurs when more than 50% of myometrium is lost at the niche scar site.
2. Width of isthmocele (c)
3. Depth of isthmocele (d)

Furthermore, we will record the shape of the defect (i.e., triangular, round, or oval). Moreover, the residual myometrial thickness will be measured. In case of isthmocele, RMT overlying the defect and the adjacent myometrial thickness fundal to the defect will be recorded. According to previous literature, the diagnosis of isthmocele was made in case of depth of the defect at least 2.00 mm in the longitudinal plan. **(Naji O et al, 2012).**

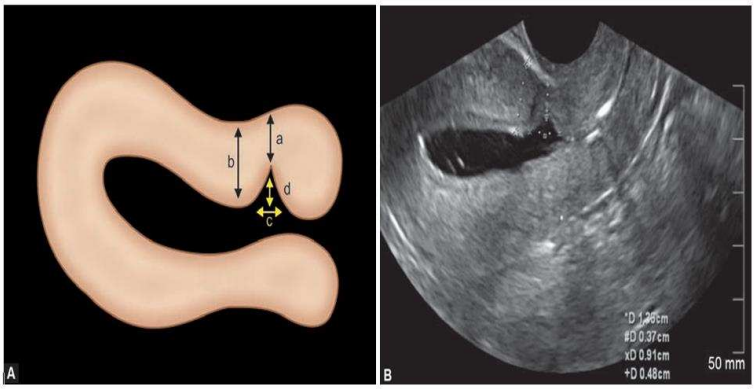

Figure 1.

Secondary outcomes:

1. Amount of blood loss.

   ABL = weight kg * age sex factor (65ml/ kg)*initial HGB(g/dl)-final HGB(g/dl) ' 12-hours postoperative". / intial HGB (g/dl) (M. E. Brecher,2003)
2. Need for extra hemostatic sutures.
3. Need for blood transfusion.

4. Wound infection.
5. Hospital stay after the delivery.
6. Post-operative fever.
   (Defined as a temperature higher than 38 c on two consecutive postoperative days or higher than 39 c on any postoperative day). **(Abdelmaseeh TA et al, 2022)**
7. Primary Postpartum hemorrhage. (Defined as Cumulative blood loss greater than 1000 mL with signs and symptoms of hypovolemia within 24 hours of the delivery).**(ASOG,2017).**

- **Statistical analysis:**

Based on the results of Saccone et al 2022 , with the mean defect width in mm in mononfilament group 2.9 ± 0.6 and in multifilament group 3.4 ±1 mm, alpha error 5% and power of study 80%, the required sample is 140 patients 70 in each group . The program for sample size calculation is STATA 10.

- **Ethical Consideration:**

This study will be done after approval of the ethical committee of the department of obstetrics and gynecology, faculty of medicine, Ain Shams University. Informed consent will be taken from all participants before recruitment in the study, and after explaining the purpose and procedures of the study. The investigator will obtain the written, signed informed consent of each subject prior to performing any study specific procedures on the subject. The investigator will retain the original signed informed consent form. All laboratory specimens, evaluation forms, reports, and other records that leave the site will not include unique personal data to maintain subject confidentiality. The study will be based on the investigator self-funding.

Protocol approval:

Before the beginning of the study and in accordance with the local regulation followed, the protocol and all the corresponding documents will be declared for ethical and research approval by the council of OB/GYN Department, Ain Shams University according to the the ethical committee

Patient right to withdraw

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Patients Enrolment Data (Form 3)
Case Record Form

Title	Description
Name	
Case Number	
Phone	
Group	
Date of enrollment	
Address	
Age	
Well informed consent	
Elective section	
Weight	
Parity	
Gestational age	
Placenta accreta spectrum during that pregnancy	
Any uterine anomalies	
Chorioamnionitis in that pregnancy	
Medical history	
Surgical history	
Pre-operative haemoglobin level	
Post-operative haemoglobin level	
Total blood loss	
Number of received blood components	
Procedure time	

ICU admission	
Hospital stay	
Post-operative fever	
Wound infection	
Trans vaginal US after 6 months ➔ Isthmocele? Yes or NO if Yes ➔ Isthmocele measurements will be obtained.	
Bladder injury in that Cesarean section	
Post-partum hemorrhage	